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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341
Fax: 504-589-6360

March 16, 1999

WARNING LETTER NO. 99-NOL-14

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Patrick F. Lukacs, President
Lukare Medical Co., Inc.
9132 Slack Road
Shreveport, Louisiana 71108

Dear Mr. Lukacs:

During the January 28, 1999, inspection of your facility located at 9132 Slack Road, Shreveport, Louisiana, our investigator documented deviations from the Current Good Manufacturing Practice regulations. These deviations cause your drug product, USP Oxygen, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) in that the controls used for the manufacturing, processing, packing or holding of this product are not in conformence with Current Good Manufacturing Practice Regulations (Title 21 Code of Federal Regulations, Part 211).

Our inspection revealed the following objectionable conditions: failure to test incoming liquid oxygen for identity and strength; failure to receive or have a valid Certificate of Analysis from the filling firm for each cryogenic home vessel filled; failure to witness the testing of incoming liquid oxygen; failure to establish either a training program or written Standard Operating Procedures (SOP's) outlining the specific areas of your firm's operations; and, failure to have a written guarantee from the supplier describing the supplier's performance of all required prefill inspections, finished product testing and labeling.

The above identification of violations is not intended to be an all inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA-483. However, it is necessary that you notify this office in writing, within 15 days of the receipt of this letter, of the steps that you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number 504-589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Hardin.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483

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